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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,323	07/09/2003	Laurence A. Cole	MBHB 03-411-A	1369

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EXAMINER	
REDDIG, PETER J	

ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/616,323	COLE, LAURENCE A.	
	Examiner	Art Unit	
	PETER J. REDDIG	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-16,46 and 47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 5-16, 46 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 4, 2008 has been entered. Claims 1, 2, 5-16, 46 and 47 are pending and under consideration.

New Grounds of Rejection

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/418, 128 fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112

for one or more claims of this application. Examiner has established a priority date of 7/9/2003 for claims 1, 2, 5-16, 46 and 47 because the claims as currently constituted recite "germ cell tumor", "saliva sample", "determining the amount of hCG in the sample wherein the amount of hCG comprises the total amount of intact hCG and ITA in the sample or comprises the total amount of intact hCG plus the amount of free β subunit of hCG and ITA", determining the total amount of ITA in the sample in an immunoassay which determines the selective binding of monoclonal B152 to ITA", "previously diagnosed as having quiescent gestation trophoblastic disease" and "the amount of hCG consists of intact hCG plus ITA" and a review of the parent Application does not reveal the claimed limitation. Applicant is invited to submit evidence pointing to the serial number, page and line where support can be found establishing an earlier priority date.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 13-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites the limitation "the patient is a women previously diagnosed as having an invasive gestational trophoblastic disease". There is insufficient antecedent basis for this limitation in claim 12 because claim 12 is drawn to a patient previously diagnosed as having quiescent gestation trophoblastic disease or a patient previously treated for a gestation

trophoblastic disease, thus it is indefinite which of these patients is a women previously diagnosed as having an invasive gestational trophoblastic disease.

Additionally, claims 14-16 recite the limitation "the gestational trophoblastic disease" in reference to claim 13. There is insufficient antecedent basis for this limitation in claim 13 because claim 13 is drawn to "an invasive gestational trophoblastic disease."

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 2, 5, 6-16, 46 and 47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting the presence or absence of invasive trophoblast cells in a patient at risk for invasive gestational trophoblastic disease or having a germ cell tumor comprising the steps of: a. obtaining a urine, serum or plasma sample from said patient; b. determining the amount of total measurable hCG in the sample by measuring hCG with the DPC Immunlite hCG test; c. determining the amount of invasive trophoblast antigen (ITA) that binds monoclonal antibody B152 in the sample in an immunoassay which binds monoclonal antibody B152 to ITA; d. determining the percentage of the amount of the total measured hCG from step b that is ITA that binds to B152, and e. determining that invasive trophoblast cells are present in the patient if the percentage is 30% or greater such that a diagnosis of gestational trophoblastic disease or the existence of a germ cell tumor may be made OR a method of diagnosing quiescent gestational trophoblastic disease in a patient previously diagnosed as having quiescent gestational trophoblastic disease or previously

treated for a gestational trophoblastic disease comprising the steps of: a. obtaining a urine, serum or plasma sample from said patient, wherein said patient has persistently low hCG titers; b. determining the amount of total measurable hCG in the sample by measuring hCG with the DPC Immunlite hCG test; c. determining the amount of invasive trophoblast antigen (ITA) that binds monoclonal antibody B152 in the sample in an immunoassay which binds monoclonal antibody B152 to ITA; d. determining the percentage of the amount of the total measured hCG from step b that is ITA that binds to B152, and e. diagnosing quiescent gestational trophoblastic disease in said patient if the percentage of total measured hCG that is ITA determined in step (d) is less than 30%, *does not* reasonably provide enablement for a method of detecting the presence or absence of invasive trophoblast cells in a patient at risk for invasive gestational trophoblastic disease or having a germ cell tumor comprising the steps of: a. obtaining a urine, saliva, serum or plasma sample from said patient; b. determining the amount of hCG in the sample wherein the amount of hCG comprises the total amount of intact hCG and ITA in the sample or comprises the total amount of intact hCG plus the amount of free β subunit of hCG and ITA in the sample; c. determining the total amount of ITA in the sample in an immunoassay which determines the selective binding of monoclonal B152 to ITA; d. determining the percentage of the amount of hCG that is ITA, and e. determining that invasive trophoblast ceils are present in the patient if the percentage is 30% or greater such that a diagnosis of gestational trophoblastic disease or the existence of a germ cell tumor may be made OR a method of diagnosing quiescent gestational trophoblastic disease in a patient previously diagnosed as having quiescent gestational trophoblastic disease or previously treated for a gestational trophoblastic disease comprising the steps of: a. obtaining a urine, saliva, serum or plasma sample from said patient, wherein said

patient has persistently low hCG titers; b. determining the amount of hCG in the sample wherein the amount of hCG comprises the total amount of intact hCG plus ITA in the sample or comprises the total amount of intact hCG plus ITA plus the amount of free β subunit of hCG in the sample; e. determining the total amount of ITA in the sample in an immunoassay which determines the selective binding of monoclonal B152 to ITA; d. determining the percentage of the amount of hCG from step b that is ITA, and e. diagnosing quiescent gestational trophoblastic disease in said patient if the percentage of total hCG that is ITA determined in step (d) is less than 30%. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Claims 1, 2, 5-11, and 46 are drawn to a method of detecting the presence or absence of invasive trophoblast cells in a patient at risk for invasive gestational trophoblastic disease or having a germ cell tumor comprising the steps of: a. obtaining a urine, saliva, serum or plasma

sample from said patient; b. determining the amount of hCG in the sample wherein the amount of hCG comprises the total amount of intact hCG and ITA in the sample or comprises the total amount of intact hCG plus the amount of free β subunit of hCG and ITA in the sample; c. determining the total amount of ITA in the sample in an immunoassay which determines the selective binding of monoclonal B152 to ITA; d. determining the percentage of the amount of hCG that is ITA, and e. determining that invasive trophoblast ceils are present in the patient if the percentage is 30% or greater such that a diagnosis of gestational trophoblastic disease or the existence of a germ cell tumor may be made.

Claims 12-16 are drawn to a method of diagnosing quiescent gestational trophoblastic disease in a patient previously diagnosed as having quiescent gestational trophoblastic disease or previously treated for a gestational trophoblastic disease comprising the steps of: a. obtaining a urine, saliva, serum or plasma sample from said patient, wherein said patient has persistently low hCG titers; b. determining the amount of hCG in the sample wherein the amount of hCG comprises the total amount of intact hCG plus ITA in the sample or comprises the total amount of intact hCG plus ITA plus the amount of free β subunit of hCG in the sample; e. determining the total amount of ITA in the sample in an immunoassay which determines the selective binding of monoclonal B152 to ITA; d. determining the percentage of the amount of hCG from step b that is ITA, and e. diagnosing quiescent gestational trophoblastic disease in said patient if the percentage of total hCG that is ITA determined in step (d) is less than 30%.

The specification teaches that obtaining serum and urine samples from women who were pregnant women and patients who had had hydatidiform mole with persistent low level of hCG and who were treated for gestational trophoblastic disease The specification teaches that ITA in

92% of the patients with persistent low level of hCG accounts for less than 5% of hCG immunoreactivity. The specification teaches that in 4 cases with rapidly rising hCG titers the proportion of total hCG that was ITA was at least 81% and in these cases trophoblastic neoplasm or malignancy was proved or suggested. See Example 1 and Table 1

The specification teaches that the USA hCG References Service observed 80 cases of persistent low levels of hCG, whether with history of hydatidiform mole or gestational trophoblastic disease (quiescent gestational trophoblastic disease) or with history of only pregnancy (unexplained elevated hCG). The specification teaches that total hCG and ITA, measured using the DPC Immunlite and Nichols Institute Diagnostics: Advantage ITA test, were measured in 53 of the 80 cases with persistent low hCG levels (Tables 7 and 5). The specification teaches that ITA was not detected (<2 IU/L) in 49 of the 53 cases with persistent low levels of hCG, and accounted for no more than 21% (<30%) of the total hCG in the remaining four cases. Additionally, the specification teaches that in sera from 13 additional patients with proven choriocarcinoma, only high proportions of ITA (>30% of total hCG) were detected (Table 4). The specification teaches that as described in Tables 7 and 3, in 7 of the 80 cases with persistent low levels of hCG, malignant disease developed and ITA results were 57% to 100% of total hCG (Table 4). The specification teaches that, putting these cases together, ITA accounted for more than 30% of total hCG immunoreactivity in 20 of 20 malignant cases, and in none of the 53 individuals with persistent elevated hCG (non-invasive disease), see p. 30, lines 6-27.

The specification teaches that samples of urine and serum were obtained from three patients suspected of having seminoma or testicular choriocarcinoma and the level of total hCG

was analyzed using DPC Immunlite test kit. The samples were then tested for immunoreactivity to ITA using the Nichols Institute Diagnostics: Advantage ITA test. In all three cases, all of the hCG immunoreactivity was due to ITA, showing that these testicular germ cell cancers, like placenta choriocarcinoma, produce ITA. The specification teaches that additionally five patients diagnosed as having ovarian germ cell malignancies (dysgerminoma) were referred to the hCG Reference Service. Samples from these five patients were also analyzed for total hCG titers (DPC Immulite), followed by testing for ITA immunoreactivity (Nichols Institute Diagnostics: Advantage ITA test). All of the hCG immunoreactivity in these patients was due to ITA. See p. 32.

One of skill in the art cannot extrapolate the teachings of the specification to the enablement of the scope of the claims because the B152 monoclonal antibody cannot determine the total amount of ITA in a sample. In particular, Birken (Tumor Biology 2005 26:131-141) teaches that because the B152 antibody recognizes a small portion of the hCG molecule, it does not measure all forms of hyperglycosylated hCG. Birken teaches that the reference to measurement of "hyperglycosylated hCG" or "ITA" is misleading until the reactivity of the various isoforms of hCG are determined. Birken teaches that it may be best to refer to isoforms measured by hCG as B-152 recognized isoforms or core 2 containing hCG isoforms. See p. 137, Forms of *'Hyperglycosylated' hCG Recognized by Antibody B152* and Fig. 9. Birken teaches that all reports on immunological measurements of hyperglycosylated hCG during the past several years have employed antibody B152, because it is the only antibody reported to detect such molecules. See p. 137-2nd col. Birken teaches that studies from the inventor's laboratory used the B152 antibody. See p. 139. Fig. 11 and ref. 50. Additionally, it is noted that Pandian et

al. (Clin. Chem. 2003 49(5): 808-810) teach that the Nichols Institute Diagnostics: Advantage ITA test used in the specification uses the B152 monoclonal antibody. See p. 808. Given that B152 does not measure all forms of hyperglycosylated hCG, one of skill in the art would not predictably be able to detect the total amount of ITA in the sample in an immunoassay which determines the selective binding of monoclonal B152 to ITA without undue experimentation.

Additionally, one of skill in the art cannot extrapolate the teachings of the specification to enableof the scope of the claims because the measurement of the total amount hCG is critical in the diagnosis of gestational trophoblastic diseases and the specification has not established a nexus between the broadly claimed method of determining the amdount of hCG and diagnosis of gestational trophoblastic diseases given that the art teaches the unpredictability of using most hCG assays for the diagnosis of gestational trophoblastic diseases. In particular, Cole et al. (Clin. Chem. 2001 47(2): 308-315, IDS) teach that hyperglycosylated hCG, nicked or non-nicked hCG, hCG minus C-terminal peptide, asialo hCG, and free β subunit may be the principal source of immuno-reactivity in trophoblastic diseases and that additional variants are present. Cole et al. teach that the inability of commercial hCG tests to fully detect these hCG variants has led to failure to detect persistent or recurrent trophoblastic diseases. See p. 309-1st col. Cole et al. teach examining several commercial tests for their ability to detect variant forms of hCG present in trophoblastic diseases and the potential of these assays to give false positives. Cole et al. teach that only that the Diagnostic Products Corp. (DPC) Immunlite hCG and the hCGβ RIA test gave consistently acceptable results. See abstract, Tables 1-5, and p. 314-2nd col. Additionally, Cole et al. teach that the DPC test used by the inventor is a chemiluminescence test, using a capture antibody and a tracer antibody directed toward different regions of the core

of hCG β subunit, but does not detect free α subunit, see, p. 309, left column and p.314, right column. Furthermore, Cole and Sutton (J. Reproductive Med. 2004 49(7): 545-53) teach that failure to detect all forms of hCG is a common cause of failure to detect active disease or recurrence or persistent of trophoblastic disease. See p. 547-1st col. Cole and Sutton teach that the competitive radioimmunoassay (RIA) is problematic because of well established problems with false positives. See p. 547-1st col., p. 550-2nd col. and p. 551-1st col. Cole and Sutton teach that the DPC Immunlite test is the only appropriate assay for monitoring patients with trophoblastic disease or cancer. See abstract and conclusion. Given the specification only teaches measuring total hCG with the DPC Immunlite test for determination of the amount of hCG that is ITA, given the problems with the other known tests for measuring the total array of hCG present in trophoblastic disease, and given that the art teaches that DPC Immunlite test is the only appropriate assay for monitoring patients with trophoblastic disease, one of skill in the art would not predictably be able to use the methods as broadly claimed without undue experimentation as measurement of total hCG with assays that incorrectly measure hCG levels or only some of the forms of hCG present in the sample would lead to incorrect determinations of the amount of hCG that is ITA. Thus, undue experimentation would be required to used the methods as broadly claimed

Additionally, one of skill in the art cannot extrapolate the teachings of the specification to enable the scope of the claims because the specification has not established a nexus between the measurement of hCG and ITA in saliva in the diagnosis of gestation trophoblastic diseases given that neither the specification nor the art of record has given sufficient guidance or direction in the measurement of hCG and ITA in saliva for the claimed diagnostic purposes or if

the percentage of hCG that ITA would be diagnostic at a 30% cut-off in saliva.

In particular, Stites et al. (Medical Immunology, 9th Ed, Appleton and Lange, 1997, pages 250-251) teach the importance of cut-off points in diagnostic tests. Stites et al. specifically teach that when any diagnostic test is used to make a decision, there is some probability of drawing an erroneous conclusion and that predictive value theory can be used to deal with this problem. The reference further teaches that diagnostic sensitivity is defined as the fraction of diseased subjects with abnormal test results and that diagnostic specificity is defined as the fraction of non-diseased subjects who have a normal laboratory test. Further, Stites et al teach that the positive predictive value is the fraction of abnormal tests that represent disease and the negative predictive value is the fraction of normal tests that represent the absence of disease (p. 251, col. 1). Stites et al. specifically teach that diagnostic sensitivity and specificity reveal something about the test *given prior knowledge about the disease status* (emphasis in the original document), whereas positive and negative predictive values *estimate the likelihood of disease given the test result* (emphasis in the original document). Clearly it is the latter case that is of interest when trying to make a diagnosis (p. 251, col. 2). The difficulty with the determination of the positive predictive value for the claimed method using salive, is that neither the specification nor the art provide guidance on whether a cut-off of 30% hCG that is ITA will be diagnostic in saliva samples. Furthermore, Cole and Sutton (J. Reproductive Med. 2004 49(7): 545-53) teach that the principal source of hCG in urine is the β-core fragment, while regular hCG dominates in regular serum samples during pregnancy. See p. 547-1st col. Thus, hCG the composition appears to vary based on the sample source. Thus, given the absence of sufficient guidance or direction that the a cut-off of 30% hCG that is ITA in saliva samples will be

diagnostic for gestational trophoblastic disease, germ cell tumors, or quiescent gestational trophoblastic disease one of skill in the art would not predictably be able to use the method as broadly claimed without undue experimentation.

The specification provides insufficient guidance with regard to these issues and provides insufficient working examples which would provide guidance to one skilled in the art and insufficient evidence has been provided which would allow one of skill in the art to predict that the invention will function as claimed with a reasonable expectation of success. For the above reasons, it appears that undue experimentation would be required to practice the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 1, 2, 5, 6-16, and 47 are rejected under 35 U.S.C. 102(a) as being anticipated by Khanlian et al. (American J. of Obstetrics and Gynecology May 2003 188:1254-9) as evidenced by Cole et al. (Clin. Chem. 1999 45:2109-2119, IDS).

Khanlian et al. teaches obtaining serum and urine samples from women who were pregnant women and patients who had had hydatidiform mole with persistent low level of hCG and who were treated for gestational trophoblastic disease. See Table 1, p. 1255 1st column, and p. 1257- left col.. Khanlian et al. teaches using the B152 antibody for measurement of ITA. See p. 1255- 2nd col. and ref. 8, which is Cole et al. (see p. 2110-1st col. and p. 2111-para. bridging

cols.). Khanlian et al. teaches determining the amount of intact hCG, free β-subunit, and β-subunit core fragments. See p. 1257-first and last paragraph. Khanlian et al. teaches measuring ITA in the patients with persistent low level of hCG and that in 92% of the cases the ITA account for less than 5% of hCG immunoreactivity. Khanlian et al. teaches that in 4 cases with rapidly rising hCG titers the proportion of total hCG that was ITA was at least 81% and in these cases trophoblastic neoplasm or malignancy was proved or suggested. Khanlian et al. teaches that that ITA effectively detected the presence or absence of invasive cells in these cases. See abstract. Khanlian et al. teaches that the findings of persistent low levels of serum hCG in the absence of pregnancy or tumor should be given the diagnosis of quiescent gestational trophoblastic disease. See p. 1259-1st col. Khanlian et al. teaches that measurement of ITA supplements hCG determinations in the management of quiescent gestational trophoblastic disease. See p. 1259-2nd col.

Khanlian et al. teaches that in examining the serum from 15 women with confirmed placental site trophoblastic tumor and choriocarcinoma the ITA accounted for approximately 100% of the total hCG and exceed 30% in all cases. See p. 1257-2nd col. and Figure. Khanlian et al. teaches that ITA has the sensitivity and specificity to differentiate a pre-invasive form of trophoblastic disease with low hCG titers from malignant disease and that ITA is new, highly reliable tumor marker for quiescent gestational trophoblastic disease. See para. bridging p. 1257 to p. 1258 and p. 1259-1st col.

6. All other rejection and objections set forth in the Office Action May 29, 2008 are withdrawn.

7. No claims allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to PETER J. REDDIG whose telephone number is (571)272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Helms Larry can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Peter J Reddig/
Examiner, Art Unit 1642